Declaration of Larry D. Sasich, Pharm.D., M.P.H., FASHP

I, Larry D. Sasich, declare as follows:

1) I am currently a consultant on drug policy and drug safety and efficacy. I have a Master's in Public Health with an emphasis in biostatistics and epidemiology and a Doctorate in Pharmacy. I have authored publications and/or presented analysis on drug safety issues. I have testified as an expert in these areas.

2) Traditional compounding pharmacies may be guided by USP <797> which sets standards for the conditions in which drug products are prepared such as sterile injection drugs used in executions. Tennessee cites USP <797> as their standard. However, the Tennessee Board of Pharmacy may waive the requirements of any applicable portion of the USP standards. This would allow for essentially no standard at all.

3) A compounded drug must be labeled with the date it is made and a Beyond Use Date (BUD).

4) USP <797> requires a high risk compounded sterile drug stored at room temperature (20-25 degrees Celsius) to be used within 24 hours. A compounded drug that is refrigerated (stored at a cold temperature not exceeding 8 degrees Celsius) must be used within 72 hours. A frozen compounded drug (stored in a solid state at temperatures between -25 to -10 degrees Celsius) must be used within 45 days.

5) USP <797> requires monitoring of controlled areas where drugs are stored. This means that compounding personnel must monitor drug storage areas, at least daily, and maintain a temperature log or temperature controlled cold chain. This also applies to the shipping of drugs. The temperature is also to be recorded each time a compounded preparation is placed into or removed from storage.

6) A compounding facility must include specific handling and exposure instructions on the exteriors of shipping containers packed with compounded sterile drug products during transit. They should secure assurance of compliance therewith from drug transporters.

7) A compounding facility is also responsible for ensuring that compounded sterile products in the drug administrator's possession maintain their quality until administered. This means that delivery and administrating personnel shall be properly trained to deliver and store the product, including procedures for daily monitoring and documentation of drug

Attachment 5

storage temperatures. A compounded sterile product should not be used if exposed to temperatures warmer than 30 degrees Celsius for more than one hour before or during their administration.

8) A failure to adhere to USP storage requirements reflects on the overall quality of the compounded drug. The risks of microbial growth, chemical degradation and cross contamination that results in decreased efficacy of the drug are increased.

9) USP <797> specifies that compounded drugs, (including midazolam, vecuronium bromide and potassium chloride), should not be used 30 days past the time they are prepared unless adequate experimental testing has been performed.

10) The federal government requires Good Manufacturing Practices (GMPs) guidelines for outsourcing pharmacies, not USP <797>.

11) Disciplinary actions against a pharmacy or pharmacist are cause for concern regarding the quality, sterility and stability of a compounded sterile drug products. In my experience, if a pharmacy is deficient in one area, they are deficient in other areas as they are all related.

12) A compounded drug product cannot be made and tested for potency, sterility and endotoxins adequately in a span of three days.

13) I have reviewed a two-page document titled "Midazolam storage and preparation instructions." The first paragraph contains some information from USP <797>. The midazolam instruction sheet does not require storage of the drug at temperatures that are compliant with USP <797>. It does not indicate the date the midazolam was prepared or its BUD. It does not contain information about the method of transportation or a cold chain record. It does not instruct the recipient to keep a record of storage, transportation, and administration temperatures or to monitor the length of time which the drug is removed from cold storage.

Compounded midazolam, vecuronium bromide and potassium chloride from bulk active pharmaceutical ingredients (APIs) are classified as high risk sterile compounded drugs. A Food and Drug Administration (FDA) qualified outsourcing facility that produces high risk compounded sterile drug products is not required to have an individual patient prescription but must adhere to federal GMP guidelines.

Attachment 5

15) A facility that prepares a compound sterile drug that is not an FDA classified outsourcing facility increases the risk of microbial growth, chemical degradation and/or contamination that results in decreased efficacy of the drug. Regardless, if a drug is compounded in a traditional pharmacy or an outsourcing facility it has been shown to be safe and effective for any purpose in human subjects.

16) Pentobarbital sodium was substituted for thiopental when thiopental was no longer sold in US. Pentobarbital is commonly used to treat seizure disorders and for use in an anesthetic cocktail.

17) Pentobarbital can be obtained through a prescription from a physician licensed to prescribe schedule 2 drugs. The prescription can be filled by any pharmacy with a DEA license to do so. If a pharmacy does not have pentobarbital in stock it could take 1-2 days to obtain it.

18) When a prescription for drugs is submitted to a pharmacy it is not common for a pharmacy to inquire about its use. A supplier of an Active Pharmaceutical Ingredient (API) for a drug does not normally inquire about the purpose for the drug being compounded.

19) Pentobarbital is manufactured in the United States for human and animal use. The API for pentobarbital is also manufactured in the United States. Pentobarbital is available in Mexico and other countries, world-wide. Pentobarbital is popular in the assisted suicide movement and can be purchased online in powder, injectable, and pill form.

20) For example, one seller in the United States will supply 20 grams of pentobarbital powder for $500.

21) A corrections officer with the Missouri Department of Correction purchased pentobarbital with cash and drove it across state lines for use in lethal injection executions.

22) A Texas public records request revealed the name of a compounding that sold pentobarbital sodium for lethal injection executions.

23) There are companies that specialize in supplying pharmaceuticals to departments of correction.

Attachment 5

I declare under penalty of perjury and pursuant to 28 U.S.C. §1746 that the forgoing is true and correct.

10/2/18

Date

Larry D. Sasich

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